1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103-465, set out as a note under section 154 of this title.

# CHAPTER 27—GOVERNMENT INTERESTS IN PATENTS

Sec.

[266. Repealed.]

267. Time for taking action in Government appli-

#### AMENDMENTS

1965—Pub. L. 89-83, §8, July 24, 1965, 79 Stat. 261, struck out item 266 "Issue of patents without fees to Government employees".

# [§ 266. Repealed. Pub. L. 89–83, § 8, July 24, 1965, 79 Stat. 261]

Section, act July 19, 1952, ch. 950, §1, 66 Stat. 811, provided for issuance of patents to government employees without fees.

#### EFFECTIVE DATE OF REPEAL

Repeal effective three months after July 24, 1965, see section 7(a) of Pub. L. 89–83, set out as an Effective Date of 1965 Amendment note under section 41 of this title.

# § 267. Time for taking action in Government applications

Notwithstanding the provisions of sections 133 and 151 of this title, the Director may extend the time for taking any action to three years, when an application has become the property of the United States and the head of the appropriate department or agency of the Government has certified to the Director that the invention disclosed therein is important to the armament or defense of the United States.

### HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §37 (R.S. 4894, amended (1) Mar. 3, 1897, ch. 391, §4, 29 Stat. 692, 693, (2) July 6, 1916, ch. 225, §1, 39 Stat. 345, 347-8, (3) Mar. 2, 1927, ch. 273, §1, 44 Stat. 1335, (4) Aug. 7, 1939, ch. 568, 53 Stat. 1264).

This provision, which appears as the last two sentences of the corresponding section of the present statute (see note to section 133) is made a separate section and rewritten in simpler form.

### AMENDMENTS

2002—Pub. L. 107-273 made technical correction to directory language of Pub. L. 106-113. See 1999 Amendment note below.

1999—Pub. L. 106–113, as amended by Pub. L. 107–273, substituted "Director" for "Commissioner" in two places.

## EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106-113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, § 4731] of Pub. L. 106-113, set out as a note under section 1 of this title.

# **CHAPTER 28—INFRINGEMENT OF PATENTS**

Sec. 271.

Infringement of patent.

Sec. 272. 273.

Temporary presence in the United States.

Defense to infringement based on earlier inventor.

#### AMENDMENTS

1999—Pub. L. 106–113, div. B, \$1000(a)(9) [title IV, \$4302(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, added item 273.

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 154 of this title.

## § 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

- (2) It shall be an act of infringement to submit—
  - (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or
  - (B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

- (3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).
- (4) For an act of infringement described in paragraph (2)—
  - (A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,
  - (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and
  - (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

- (f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.
- (2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial

noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

- (g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after-
  - (1) it is materially changed by subsequent processes: or
  - (2) it becomes a trivial and nonessential component of another product.
- (h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.
- (i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

## HISTORICAL AND REVISION NOTES

The first paragraph of this section is declaratory only, defining infringement.

Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to these paragraphs, see preliminary general description of bill. One who actively induces infringement as by aiding and abetting the same is liable as an infringer, and so is one who sells a component part of a patented invention or material or apparatus for use therein knowing the same to be especially made or especially adapted for use in the infringement of the patent except in the case of a staple article or commodity of commerce having other uses. A patentee is not deemed to have misused his patent solely by reason of doing anything authorized by the section.

## REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(1), (2), is act June 25, 1938, ch. 675, 52

Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Sections 505(b)(2), 505(j), and 512 of that Act are classified, respectively, to sections 355(b)(2), 355(j), and 360b of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Act of March 4, 1913, referred to in subsec. (e)(1), (2), is act Mar. 4, 1913, ch. 145, 37 Stat. 828, as amended. The provisions of such act relating to viruses, etc., applicable to domestic animals, popularly known as the Virus-Serum-Toxin Act, are contained in the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, at 37 Stat. 832, and are classified generally to chapter 5 (§151 et seq.) of Title 21. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

#### AMENDMENTS

1994—Subsec. (a). Pub. L. 103–465, §533(a)(1), inserted ", offers to sell," after "uses" and "or imports into the United States any patented invention" after "the United States".

Subsec. (c). Pub. L. 103-465, §533(a)(2), substituted "offers to sell or sells within the United States or imports into the United States" for "sells".

Subsec. (e)(1), Pub. L. 103-465, §533(a)(3)(A), sub-

Subsec. (e)(1). Pub. L. 103-465, §533(a)(3)(A), substituted "offer to sell, or sell within the United States or import into the United States" for "or sell".

Subsec. (e)(3). Pub. L. 103-465, \$533(a)(3)(B), substituted "offering to sell, or selling within the United States or importing into the United States" for "or selling".

Subsec. (e)(4)(B), (C). Pub. L. 103-465, \$533(a)(3)(C), (D), substituted "offer to sell, or sale within the United States or importation into the United States" for "or sale".

Subsec. (g). Pub. L. 103-465, §533(a)(4), substituted "offers to sell, sells," for "sells", "importation, offer to sell, sale," for "importation, sale,", and "other use, offer to sell, or" for "other use or".

Subsec. (i). Pub. L. 103-465, \$533(a)(5), added subsec. (i).

1992—Subsec. (h). Pub. L. 102–560 added subsec. (h). 1988—Subsec. (d). Pub. L. 100–703 added cls. (4) and (5).

Subsec. (e)(1). Pub. L. 100-670, \$201(i)(1), inserted "which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques" after "March 4, 1913)" and "or veterinary biological products" after "sale of drugs".

Subsec. (e)(2). Pub. L. 100-670, §201(i)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: 'It shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.'

Subsec. (e)(4). Pub. L. 100-670, §201(i)(3), inserted "or veterinary biological product" after "drug" in subpars. (A) to (C).

Subsec. (g). Pub. L. 100–418 added subsec. (g). 1984—Subsec. (e). Pub. L. 98–417 added subsec. (e). Subsec. (f). Pub. L. 98–622 added subsec. (f).

### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103–465, set out as a note under section 154 of this title.

## EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102-560 effective with respect to violations that occur on or after Oct. 28, 1992, see

section 4 of Pub. L. 102-560, set out as a note under section 2541 of Title 7, Agriculture.

#### EFFECTIVE DATE OF 1988 AMENDMENTS

Section 202 of title II of Pub. L. 100-703 provided that: "The amendment made by this title [amending this section] shall apply only to cases filed on or after the date of the enactment of this Act [Nov. 19, 1988]."

Section 9006 of Pub. L. 100-418 provided that:

"(a) IN GENERAL.—The amendments made by this subtitle [subtitle A (§§ 9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending this section and sections 154 and 287 of this title] take effect 6 months after the date of enactment of this Act [Aug. 23, 1988] and, subject to subsections (b) and (c), shall apply only with respect to products made or imported after the effective date of the amendments made by this subtitle.

(b) EXCEPTIONS.—The amendments made by this subtitle shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on January 1, 1988, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This subsection shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a process patent enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

"(c) RETENTION OF OTHER REMEDIES.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930 [19 U.S.C. 1337], or under any other provision of law."

### EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–622 applicable only to the supplying, or causing to be supplied, of any component or components of a patented invention after Nov. 8, 1984, see section 106(c) of Pub. L. 98–622, set out as a note under section 103 of this title.

REPORTS TO CONGRESS; EFFECT ON DOMESTIC INDUSTRIES OF PROCESS PATENT AMENDMENTS ACT OF 1988

Pub. L. 100–418, title IX, §9007, Aug. 23, 1988, 102 Stat. 1567, provided that the Secretary of Commerce was to make annual reports to Congress covering each of the successive five 1-year periods beginning 6 months after Aug. 23, 1988, on the effect of the amendments made by subtitle A (§§9001–9007) of title IX of Pub. L. 100–418, enacting section 295 of this title and amending sections 154, 271, and 287 of this title, on those domestic industries that submit complaints to the Department of Commerce alleging that their legitimate sources of supply have been adversely affected by the amendments.

# SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 157, 273, 287, 296 of this title; title 21 sections 355, 360b.

## § 272. Temporary presence in the United States

The use of any invention in any vessel, aircraft or vehicle of any country which affords similar privileges to vessels, aircraft or vehicles of the United States, entering the United States temporarily or accidentally, shall not constitute infringement of any patent, if the invention is used exclusively for the needs of the vessel, aircraft or vehicle and is not offered for sale or sold

in or used for the manufacture of anything to be sold in or exported from the United States.

(July 19, 1952, ch. 950, 66 Stat. 812; Pub. L. 103-465, title V, §533(b)(4), Dec. 8, 1994, 108 Stat. 4989.)

#### HISTORICAL AND REVISION NOTES

This section follows the requirement of the International Convention for the Protection of Industrial Property, to which the United States is a party, and also codifies the holding of the Supreme Court that use of a patented invention on board a foreign ship does not infringe a patent.

#### AMENDMENTS

 $1994—Pub.\ L.\ 103–465$  substituted "not offered for sale or sold" for "not sold".

#### EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-465 effective on date that is one year after date on which the WTO Agreement enters into force with respect to the United States [Jan. 1, 1995], with provisions relating to earliest filed patent application, see section 534(a), (b)(3) of Pub. L. 103-465, set out as a note under section 154 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 157 of this title; title 42 section 2457.

# § 273. Defense to infringement based on earlier inventor

- (a) DEFINITIONS.—For purposes of this section—  $\,$ 
  - (1) the terms "commercially used" and "commercial use" mean use of a method in the United States, so long as such use is in connection with an internal commercial use or an actual arm's-length sale or other arm'slength commercial transfer of a useful end result, whether or not the subject matter at issue is accessible to or otherwise known to the public, except that the subject matter for which commercial marketing or use is subject to a premarketing regulatory review period during which the safety or efficacy of the subject matter is established, including any period specified in section 156(g), shall be deemed "commercially used" and in "commercial use" during such regulatory review period;
  - (2) in the case of activities performed by a nonprofit research laboratory, or nonprofit entity such as a university, research center, or hospital, a use for which the public is the intended beneficiary shall be considered to be a use described in paragraph (1), except that the
    - (A) may be asserted as a defense under this section only for continued use by and in the laboratory or nonprofit entity; and
    - (B) may not be asserted as a defense with respect to any subsequent commercialization or use outside such laboratory or non-profit entity;
  - (3) the term "method" means a method of doing or conducting business; and
  - (4) the "effective filing date" of a patent is the earlier of the actual filing date of the application for the patent or the filing date of any earlier United States, foreign, or international application to which the subject matter at issue is entitled under section 119, 120, or 365 of this title.

- (b) Defense to Infringement.—
- (1) IN GENERAL.—It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims for a method in the patent being asserted against a person, if such person had, acting in good faith, actually reduced the subject matter to practice at least 1 year before the effective filing date of such patent, and commercially used the subject matter before the effective filing date of such patent.
- the effective filing date of such patent.
  (2) EXHAUSTION OF RIGHT.—The sale or other disposition of a useful end product produced by a patented method, by a person entitled to assert a defense under this section with respect to that useful end result shall exhaust the patent owner's rights under the patent to the extent such rights would have been exhausted had such sale or other disposition been made by the patent owner.
- (3) LIMITATIONS AND QUALIFICATIONS OF DEFENSE.—The defense to infringement under this section is subject to the following:
- (A) PATENT.—A person may not assert the defense under this section unless the invention for which the defense is asserted is for a method.
- (B) DERIVATION.—A person may not assert the defense under this section if the subject matter on which the defense is based was derived from the patentee or persons in privity with the patentee.
- (C) NOT A GENERAL LICENSE.—The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter claimed in the patent with respect to which the person can assert a defense under this chapter, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.
- (4) BURDEN OF PROOF.—A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.
- (5) ABANDONMENT OF USE.—A person who has abandoned commercial use of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense under this section with respect to actions taken after the date of such abandonment.
- (6) Personal defense.—The defense under this section may be asserted only by the person who performed the acts necessary to establish the defense and, except for any transfer to the patent owner, the right to assert the defense shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.
- (7) LIMITATION ON SITES.—A defense under this section, when acquired as part of a good faith assignment or transfer of an entire en-

terprise or line of business to which the defense relates, may only be asserted for uses at sites where the subject matter that would otherwise infringe one or more of the claims is in use before the later of the effective filing date of the patent or the date of the assignment or transfer of such enterprise or line of business.

- (8) Unsuccessful assertion of defense.—If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285 of this title.
- (9) INVALIDITY.—A patent shall not be deemed to be invalid under section 102 or 103 of this title solely because a defense is raised or established under this section.

(Added Pub. L. 106–113, div. B, 1000(a)(9) [title IV, 4302(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A-555.)

#### EFFECTIVE DATE

Pub. L. 106–113, div. B, \$1000(a)(9) [title IV, subtitle C, \$4303], Nov. 29, 1999, 113 Stat. 1536, 1501A–557, provided that: "This subtitle [enacting this section and provisions set out as a note under section 1 of this title] and the amendments made by this subtitle shall take effect on the date of the enactment of this Act [Nov. 29, 1999], but shall not apply to any action for infringement that is pending on such date of enactment or with respect to any subject matter for which an adjudication of infringement, including a consent judgment, has been made before such date of enactment."

## CHAPTER 29—REMEDIES FOR INFRINGE-MENT OF PATENT, AND OTHER ACTIONS

MINI	OF TATEMI, AND OTHER ACTIONS
Sec.	
281.	Remedy for infringement of patent.
282.	Presumption of validity; defenses.
283.	Injunction.
284.	Damages.
285.	Attorney fees.
286.	Time limitation on damages.
287.	Limitation on damages and other remedies;
	marking and notice.
288.	Action for infringement of a patent con-
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289.	Additional remedy for infringement of design
	patent.
290.	Notice of patent suits.
291.	Interfering patents.
292.	False marking.
293.	Nonresident patentee, service and notice. <sup>1</sup>
294.	Voluntary arbitration.
295.	Presumption: Product made by patented
	process.
296.	Liability of States, instrumentalities of
	States, and State officials for infringement
	of patents.
297.	Improper and deceptive invention promotion.
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### AMENDMENTS

1999—Pub. L. 106–113, div. B, 1000(a)(9) [title IV, 100(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–554, added item 297.

1992—Pub. L. 102–560,  $\S\,2(\mathrm{b}),$  Oct. 28, 1992, 106 Stat. 4230, added item 296.

1988—Pub. L. 100–418, title IX, §§ 9004(b), 9005(b), Aug. 23, 1988, 102 Stat. 1566, inserted "and other remedies" in item 287 and added item 295.

1982—Pub. L. 97–247, 17(b)(2), Aug. 27, 1982, 96 Stat. 323, added item 294.

#### CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 154, 207 of this title; title 15 section 3710a.

### §281. Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

(July 19, 1952, ch. 950, 66 Stat. 812.)

### HISTORICAL AND REVISION NOTES

Based on Title 35, U.S.C., 1946 ed., §§ 67 and 70, part (R.S. 4919; R.S. 4921, amended (1) Mar. 3, 1897, ch. 391, §6, 29 Stat. 694, (2) Feb. 18, 1922, ch. 58, §8, 42 Stat. 392, (3) Aug. 1, 1946, ch. 726, §1, 60 Stat. 778).

The corresponding two sections of existing law are divided among sections 281, 283, 284, 285, 286 and 289 with some changes in language. Section 281 serves as an introduction or preamble to the following sections, the modern term civil action is used, there would be, of course, a right to a jury trial when no injunction is sought.

#### SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 157, 287 of this title

#### § 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

- (1) Noninfringement, absence of liability for infringement or unenforceability,
- (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,
- (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
- (4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the

<sup>&</sup>lt;sup>1</sup>So in original. Does not conform to section catchline.